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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/578,361 | 05/05/2006 | Kuniaki Yamataka | 2006_0637A | 6912 |
| 513 7590 04/17/2009 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503 | | | | |
| EXAMINER | | | | |
| MALEKZADEH, SEYED MASOUD | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1791 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 04/17/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/578,361

Applicant(s)

YAMANAKA ET AL.

Examiner

SEYED M. MALEKZADEH

Art Unit

1791

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/17/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 15, 16 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-14 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 05/05/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims **1- 20** were **restricted**.

Claims **4- 14 and 17- 19** are **elected**.

Claims **1- 3, 15-16, and 20** are **withdrawn**.

Applicant's **election of group II, claims 4- 14 and 17- 19**, in the reply filed on 03/17/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse**. (MPEP § 818.03(a))

Claims 1-3, 15- 16, and 20 are **withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a **non-elected group I**, there being no allowable generic or linking claim.

In the office action, mailed on 02/24/2009, claim 16 was inadvertently included with group II in which was not cited properly. Claim 16 is dependent to the nonelected claim 2, and thus it is drawn to the first group. Therefore, hereby, claim 16 is considered as a nonelected claim.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

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The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The filed abstract on 05/05/2006 is objected because it is not in a proper format and includes more than 150 words.

Claim Objections

Claim 4 is objected to because of the following informalities: claim 4 recites "the diameter D2 of the liquid drops in the inlet part" (see line 10); wherein identifying diameter of the liquid drops with D2 does not correspond to the specification. According to the specification the diameter of the liquid drops are identified by D0. Appropriate correction is required.

35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **4- 14 and 17- 19** are rejected under 35 U.S.C. 112, **second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the flow rate of hardening liquid" in the eighth line. There is insufficient antecedent basis for this limitation in the claim because prior to the cited limitation, the claim fails to clearly define a flow rate or an apparatus structure which associates with the flow rate of the hardening liquid.

Claim 4 recites the limitation "the diameter D1 of the largest circle" in the eighth line. There is insufficient antecedent basis for this limitation in the claim because prior to the cited limitation, the claim fails to clearly define "a diameter D1 of the largest circle" for the deformation section.

Claim 4 recites "the largest circle can be inscribed" in the ninth line of the claim which renders the claim vague and indefinite. The phrase "can be" fails to distinctly claim if the largest circle is actually inscribed in the inner periphery of the deformation section or not. Therefore, the claim is indefinite and fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the inner periphery of the deformation section" in the ninth line. There is insufficient antecedent basis for this limitation in the claim because prior to the cited limitation, the claim fails to clearly point out "an inner periphery of the deformation section"

Claim 4 recites "a deformation section having a cross sectional area smaller than the inlet part" which renders the claim vague and indefinite because the recitation fails to clearly define the cross sectional area of the deformation section is smaller compare to which dimensional element of the inlet part such as area, length, wide, or diameter.

Claims 6- 8 and 17- 19 recite the limitation of "the cross section of the deformation"; there is insufficient antecedent basis for this limitation in the claim because prior to the cited limitation, the claim or precedent claims fail to clearly point out "a cross section of the deformation section"

Claims 9- 10 recite the limitation "the diameter of the largest circle" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim because prior to the cited limitation, the claim fails to clearly defines "a diameter of the largest circle"

Claims 9- 10 recite "the largest circle can be inscribed" in the ninth line of the claim which renders the claim vague and indefinite. The phrase "can be" fails to distinctly claim if the largest circle is actually inscribed in the inner periphery of the deformation section or not.

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Therefore, the claim is indefinite and fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9- 10 recite the limitation "the inner periphery of the deformation section" in the second and third lines. There is insufficient antecedent basis for this limitation in the claim because prior to the cited limitation, the claim fails to clearly define "an inner periphery of the deformation section"

Claims 11- 12 recite the limitation "the cross sectional area S" in the second and third lines of the claims. There is insufficient antecedent basis for this limitation in the claim because prior to the cited limitation, the claim fails to clearly define "a cross sectional area S"

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4- 5 and 9- 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al (US 4,717,049)

Green et al (US '049) teach an apparatus for producing uniform droplets of a liquid as a seamless capsule manufacturing device in which the forming apparatus comprises a capillary tube having a liquid receiving end and an open tip, means for supplying and controlling the flow of the liquid to the receiving end, an outer concentric tube having a converging-diverging venturi nozzle at the bottom in which the tip of the capillary tube being positioned in the throat of the venturi, a source of gas supplied to the outer tube, and means for regulating the flow of gas through said venturi nozzle to control the formation of droplets from the tip of the capillary tube. (See column 4, lines 42- 55)

Furthermore, Green et al (US '049) disclose the apparatus includes an outer concentric tube (22) with a venturi (23), both together, as a flow passage tube in which the flow passage tube includes an inlet part (22) and a deformation section (23), a tube (20) with the capillary tube (19) together as a nozzle received in the inlet part (22) in which a venturi (23) as a deformation section is connected at the bottom of the inlet part (22), and the deformation section (23) includes a smaller cross sectional area than the cross sectional area of the inlet part (22), and the diameter (D1) of the narrowest circle in the inner periphery of the deformation section (23) which is throat (23) is larger than the diameter of the capillary tube (19) or liquid drops and the diameter (D2) of the inlet part (22) is larger than the diameter of the deformation section. (See column 4, lines 42- 55, column 2, lines 57- 68, column 3, lines 1- 20; and figure 2)

Also, Green et al (US '049) teach the metering pump (21) is connected to the tube (20) to provide fuel from the metering pump into the tube (20) and a flow controller (26) that regulates the flow of gas through the venturi to control the formation of droplets from the tip of capillary tube.

Green et al (US '049) discloses the deformation section is arranged downstream relative to the inlet part.

Also, Green et al (US '049) disclose the critical relationship between the size of the venturi throat and the diameter of the capillary tube will depend on the type of droplets to be produced. The capillary tube (19) has an inside diameter in the range of about 0.001" to 0.035" and an outside diameter of 0.005" to 0.05". The outer concentric tube (22) includes an inside diameter in the range of 0.1" to 2", and the throat of the venturi (23), as the deformation section includes an inside diameter in the range of 0.01" to 0.075" (See lines 29- 37, column 3), wherein according to the teaching of the prior art that "capillary includes an inside diameter of 0.004", it is conferred that the diameter of the ejected droplets is also 0.004". Therefore, the above teachings satisfy the claims requirement for claims 9- 12 in which the D1, as the largest circle in the inner periphery of the deformation section, is greater than the diameter D0 of the ejected liquid drops and not greater than three times of the diameter D0 of the ejected liquid drops in the inlet part, and the D1 is between one sixth times and two third times of the inner diameter

D2 of the flow passage tube in the inlet part. Further, Green et al (US '049) teach the cross sectional area (S) of the deformation section is in a range of $(\pi/4)D_0^2 < S \leq (9\pi/4)D_0^2$ and further, the cross sectional area (S) of the deformation section is between one thirty sixth times and four ninth times of the cross sectional area of the flow passage tube in the inlet part.

Furthermore, Green et al (US '049) teaches a method of producing uniform droplets of a liquid comprising supplying a stream of gas to a concentric tube, the stream of gas flowing through the concentric tube, supplying the liquid to a first end of a capillary tube as a part of the nozzle positioned in the concentric tube, and the step of passing the stream of uniform droplets through the inlet part (22) and the deformation section (23), (See column 2, lines 9- 25) Therefore, the prior art teaches a seamless capsule manufacturing method characterized by manufacturing non-spherical seamless capsules by means of the disclosed seamless capsule manufacturing device.

Claim 4 recites "containing hardening liquid for hardening at least a surface part of each liquid drop formed from the liquid" (see lines 3-4); further, **claim 4** recites "deforming each liquid drop to show an aspheric profile by changing the flow rate of hardening liquid and the diameter D1 of the largest circle that can be inscribed in the inner periphery of the deformation section is larger than the diameter D2 of the liquid drops in

the inlet part.” (See lines 7- 10) Also **claim 5** disclose “where the ejected liquid drops arrive in a sol state” (See line 3), wherein the above recitations are directed to an operation of the claimed apparatus to change the flow rate of hardening liquid and the result of the operating the claimed apparatus on the obtained product

Moreover, **claim 9** recites “if the diameter of the largest circle that can be inscribed in the inner periphery of the deformation section is D_1 , the D_1 is greater than the diameter D_0 of the ejected liquid drops and not greater than three times of the diameter D_0 of the ejected liquid drops in the inlet part ($D_0 < D_1 \leq 3D_0$)”; (See lines 3- 5) **claim 10** teaches “if the diameter of the largest circle that can be inscribed in the inner periphery of the deformation section is D_1 , the D_1 is between one sixth time and two third times of the inner diameter (D_2) of the flow passage tube in the inlet part.” (See lines 3-4) also **claim 11** teaches “if the diameter of the ejected liquid drops in the inlet part is D_0 , the cross sectional area S of the deformation section is defined to be within a range of $(\pi/4)D_0^2 < S \leq (9\pi/4)D_0^2$; further, **claim 12** recites “the cross sectional area S of the deformation section is between one thirty sixth times and four ninth times of the cross sectional area of the flow passage tube in the inlet part.” wherein also these recitations disclose the operational features of the apparatus through adjusting the nozzle which results in sizing the diameter of the ejected droplet.

Therefore, the above recitations do not provide further structural limitations to the claimed apparatus. Therefore, the recitations are directed to the **intended use** of the claimed apparatus and no or little patentable weight is given to the above citations.

Intended use has been continuously held not to be germane to determining the patentability of the apparatus, *In re Finsterwalder*, 168 USPQ 530.

The manner or method in which a machine is to be utilized is not germane to the issue of patentability of the machine itself, *In re Casey*, 152 USPQ 235,238.

Purpose to which apparatus is to be put and expression relating apparatus to contents thereof during intended operation are not significant in determining patentability of an apparatus claim, *Ex parte Thibault*, 164 USPQ 666.

A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations, *EX parte Masham*, 2 USPQ2d 1647.

The prior art, thus, meets all the claim limitations, and therefore, Green et al (US '049) anticipates the claims 4- 5 and 9- 13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6- 8 and 17- 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al (US '049) in view of Kosaka et al (US 5,209,978)

Green et al (US '049) teach all the structural limitations of a seamless capsule manufacturing device, as claimed in claims 4- 5, 9- 13. **However**, the prior art is **silent** about the shape of the cross section of the deformation section, as claimed in claims 6- 8 and 17- 19.

In the analogous art, Kosaka et al (US '978) teach a seamless capsule manufacturing device comprising a plurality of tanks (1- 4) for

holding liquid substances for manufacturing soft capsules, a composite nozzle (5) as a duplex nozzle comprising outside nozzles (51 and 52) having a semielliptical cross sectional shape resulting from partitioning an elliptical tube by a portioning wall (50) at its center and inside nozzles (5a and 5b) of a smaller diameter disposed centrally in the outside nozzles (51 and 52), respectively in which the outside nozzles (51 and 52) communicate with the tanks 1 and 2, and the inside nozzles (5a and 5b) communicate with the tanks 3 and 4. The composite nozzle (5) faces downwardly along a downwardly flowing stream of a liquid medium within a capsule forming tank (6). (See column 2, lines 48- 68) Further, Kosaka et al (US 5,209,978) teach the droplets (f) formed by nozzle (5) enters a capsule forming tank (6) passing through a capsule recovery tube (61) to transfer the droplets (f) into a recovery hopper (7). (See column 3, lines 14- 17)

Therefore, Kosaka et al (US '978) disclose the cross section of the composite nozzle, as a tube member in the capsule manufacturing device which is in an elliptical or polygonal shape, or shows a contour having one or more than one straight lines. (See figures 2, 6, 10, and 8)

It would have been obvious for one of ordinary skill in the art at the time of applicant's invention to modify the device as taught by Green et al (US '049) through providing a deformation section with an elliptic or polygonal shape or a cross section with a contour including one or more straight lines, as suggested Kosaka et al (US '978) since such a mere

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change in the shape of the apparatus member without affecting the functioning of the apparatus part would have been within the level of the ordinary skill in the art; also see *In re Dailey et al*, 149 USPQ 47; *Eskimo pie Corp. v. levous et al*, 3 USPQ 23.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al (US '049) in view of Yeo et al. (US 2002/0160109)

Green et al. (US '049) teaches all the process steps of a seamless capsule manufacturing method as discussed above. **However**, Green et al. (US '049) **fail** to teach bringing the seamless capsules into contact with the ethanol type processing liquid, as claimed in claim 14.

In the analogous art, Yeo et al (US '109) teach a method for preparing an encapsulated composition through providing an aqueous solution composed of water and a core substance dissolved therein, providing a polymer solution composed of a water-miscible solvent and a water-insoluble polymer dissolved therein, forming a droplet of the aqueous solution containing the core substance, and admixing the droplet of aqueous solution with at least a portion of the polymer solution under conditions permitting the water-insoluble polymer to deposit as at least one layer on the core substance, wherein the aqueous solution includes a water-miscible solvent which is selected from the group consisting of ethanol in which ethanol causes partial dehydrating

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the aqueous polymer solution, and concentrating the water soluble polymer in the water to form a polymer rich phase. (See paragraph [0017])

It would have been obvious for one of ordinary skill in the art at the time of applicant's invention to modify the process steps of a seamless capsule manufacturing method as taught by Green et al. (US '049) through bringing the seamless capsules into contact with the ethanol type processing liquid **in order to** dehydrate the aqueous polymer solution, and to increase the concentration of the soluble polymer in the water to form a polymer rich phase, as suggested by Yeo et al (US '109).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Masoud Malekzadeh whose telephone number is 571-272-6215. The examiner can normally be reached on Monday – Friday at 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven P. Griffin, can be reached on (571) 272-1189. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SEYED M. MALEKZADEH/

Examiner, Art Unit 1791

/Eric Hug/

Primary Examiner, Art Unit 1791